

REMARKS

This is in response to the Office Action of February 6, 2008. Claims 1-6 are pending in the present application.

In the Office Action, the Examiner: (1) rejected claims 1-6 under 35 USC 103 as being unpatentable over US 5,954,971 to Pages et al. in view of US 5,350,357 to Kamen et al. and further in view of US 4,750,868 to Lundback.

The Pending Claims Would Not Have Been Obvious Over US 5,954,971 to Pages in view of US 5,350,357 to Kamen and further in view of US 4,750,868 to Lundback

Turning first to the rejection of claims 1-6 under 35 USC § 103, it is respectfully submitted that independent claim 1 and the respective dependent claims would not have been obvious over the cited references.

Specifically, independent claim 1 requires, among other things, a blood processing system comprising a filter for removing leukocytes from blood, first and second fluid pressure actuated pump stations, and a fluid pressure actuator. The actuator operates to selectively apply fluid pressure pump strokes in tandem to the first and second pump stations to convey fluid from a source to the filter. The fluid pressure actuator includes a control function to switch between a first flow mode, in which the pump strokes draw a fluid volume into the first pump station from the source and expel a fluid volume from the second pump station to the filter, and a second flow mode, in which the pump strokes draw a fluid volume into the second pump station from the source and expel a fluid volume from the first pump station to the filter. The control

function operates to synchronize the pump strokes so that fluid flow from the source is essentially continuous while fluid flow to the filter is pulsatile.

In contrast, the cited references do not, either alone or in combination, describe or suggest a blood processing system comprising (1) a blood processing system comprising first and second fluid pressure actuated pump stations, (2) a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter, (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, or (4) a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile. Applicants discuss each of the Examiner's objections, in turn, below.

Pages Does Not Describe A Blood Processing System Comprising First And Second Fluid Pressure Actuated Pump Stations

First, Pages does not describe a blood processing system comprising first and second fluid pressure actuated pump stations as required by claim 1. In contrast, Pages discloses a fluid circuit including a peristaltic pump 132 that operates on tubing line 130 to move fluid throughout the system, or similarly, a pair of peristaltic pumps

232a and 232b that operate on tubing line 230. See Pages, col. 3, lines 45-50 and Figure 1 and col. 6, lines 19-22 and Figure 2. Thus, Pages simply does not disclose or even contemplate first and second fluid pressure actuated pump stations as required by claim 1.

Pages Does Not Describe A Blood Processing System In Which A Fluid Pressure Actuator Operates To Selectively Apply Fluid Pressure Actuated Pump Strokes In Tandem To First And Second Pump Stations, And Is Not Properly Combinable With Kamen To Render The Claimed Subject Matter Obvious

Second, Pages does not describe a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter, and the Examiner expressly acknowledges this fact in the Office Action.

While the Examiner expressly acknowledges the lack of disclosure of this claimed feature in Pages, the Examiner then suggests combining the teachings of Pages with Kamen to achieve the claimed subject matter. However, contrary to the Examiner's suggestion, it is respectfully submitted that the Kamen patent is not properly combinable with Pages to render the claimed subject matter obvious. In particular, even if one were to combine the dialysis system disclosed in Kamen with the blood processing system described in Pages, the resulting device would still not have the features of the claimed blood processing system.

In particular, when determining whether the claimed invention would have been obvious under §103, a prior art reference must be considered in its entirety, including

disclosures that teach away from the claims. W. L. Gore & Associates, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983). Also see M.P.E.P. 2141.21 (VI). In this regard, the Examiner has cited the Kamen reference and suggested that it teaches the claimed feature of an actuator operating pump strokes in tandem to first and second pump stations. However, when considered in its entirety, it expressly teaches away from another claimed feature – that is, the claimed feature of an actuator including a control function to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile. In fact, Kamen actually teaches the opposite. For example, Kamen specifically teaches that pump chambers P1 and P2 operate to provide continuous, not pulsatile, flow. In particular, Kamen describes a dialysis system including a cassette with pump chambers P1 and P2, which pump in a sequence such that heated dialysate is always introduced into the pump chambers P1 and P2 while heated dialysate is always discharged through the pump chambers P1 and P2 to the patient. See Kamen, col. 32, lines 6-10. Thus, fluid flow into and from pump chambers P1 and P2 is essentially continuous. This would be contrary to the claimed blood processing system which requires a control function that synchronizes pump strokes so that fluid flow to a filter is pulsatile, as set forth in claim 1.

Thus, while the Examiner has cited Kamen as allegedly describing operating first and second pump stations in tandem, it actually teaches away from another claimed feature. Kamen, therefore, is not properly combinable with Pages for at least the reason that it is improper to combine references that teach away from the claimed invention. See M.P.E.P. 2145(X). For at least this reason, it is respectfully submitted

that it would not have been obvious to one skilled in the art to combine Pages with Kamen to reach the present invention.

Pages Does Not Describe A Fluid Pressure Actuator Including A Control Function To Switch Between A First Mode and A Second Mode

Third, Pages does not describe a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, as required by claim 1. For example, as described in further detail in the specification of the present application, the fluid pressure actuator switches between a first and second flow mode, allowing, for example, pump stations PP3 and PP4 to “toggle” or alternate draw and expel functions. See page 34, para. [0531].

It is respectfully submitted that the above-described claimed feature is not found nor contemplated in Pages. While Pages describes a draw cycle in which whole blood drawn from a donor is centrifuged into its components and passed through a filter, and also describes operating the cycle a second time, if necessary, to process a particular volume of blood or components, each of these cycles operates fully and independently from one another. See col. 8, lines 19-25 of Pages which describes that “when the centrifuge bowl 210 is emptied or the predetermined volume of product processed, apparatus 200 begins a second draw cycle identical to that [first cycle] described

above." Thus, only when an entire "first" draw cycle is complete can the "second" cycle begin. No matter how the system in Pages is programmed or what blood processing procedure is intended to be performed, Pages does not describe a fluid pressure actuator including a control function as presently claimed, nor is Pages even capable of switching between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter as required by claim 1.

Pages Does Not Describe A Fluid Pressure Actuator That Synchronizes Pump Strokes So That Fluid Flow From The Source Is Continuous While Fluid Flow To The Filter Is Pulsatile, And Is Not Properly Combinable With Lundback To Render The Claimed Subject Matter Obvious

Fourth, Pages does not describe a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile, and the Examiner expressly acknowledges this fact in the Office Action. Further, the Lundback '868 patent does not disclose any of the subject matter missing from the Pages patent and is not properly combinable with Pages to render the claimed subject matter obvious.

As noted above, Pages does not describe various structural features as set forth in the pending claims. Further, and as acknowledged by the Office Action, Pages does not disclose a fluid pressure actuator including a control function that synchronizes

pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile. Accordingly, even if one were to combine the Lundback system, which describes generally a *single* pump that can be used in industry, mining, and the like, the resulting device would still not have the features of the claimed blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to *first and second* pump stations to convey fluid from a source to a filter, and wherein the actuator includes a control function operating to synchronize the pump strokes so that fluid flow from a source is essentially continuous and fluid flow to a filter is pulsatile.

Therefore, it is submitted that it would not have been obvious to one skilled in the art to combine the features of the Pages patent with the pump described in Lundback to reach the present invention.

Conclusion Regarding Non-Obviousness

Accordingly, it is respectfully submitted that there is no description or suggestion in Pages of (1) a blood processing system comprising first and second fluid pressure actuated pump stations, (2) a blood processing system in which a fluid pressure actuator operates to selectively apply fluid pressure pump strokes in tandem to first and second pump stations to convey fluid from a source to a filter, (3) a fluid pressure actuator that includes a control function to switch between a first flow mode, in which pump strokes draw a fluid volume into a first pump station from a source and expel a

fluid volume from a second pump station to a filter, and a second flow mode, in which pump strokes draw a fluid volume into a second pump station from a source and expel a fluid volume from a first pump station to a filter, or (4) a control function operating to synchronize pump strokes so that fluid flow from a source is essentially continuous while fluid flow to a filter is pulsatile as required by claim 1.

For at least the reasons described above, it is respectfully submitted that claims 1-6 would not have been obvious over Pages, either alone or in combination with Kamen and/or Lundback. Accordingly, the withdrawal of the rejections and reconsideration and allowance of the claims are respectfully requested.

Respectfully submitted,

Date: May 1, 2008

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